

NEPHROS

Instructions for Use Part #: 70-0112

HydraGuard 10" UltraFilter – Flush

Introduction

Information on this sheet must be read before the use of this device to ensure safe and effective operation.

Recommended Storage: Between 5 and 35°C (41 and 95°F).

Indications

Description: The HydraGuard 10" UltraFilter - Flush is a hollow fiber ultrafilter that retains bacteria, viruses, and endotoxin from water.

Indications for Use: The HydraGuard 10" UltraFilter - Flush is intended to be used to filter EPA quality drinking water. The filter retains bacteria, viruses and endotoxin. By providing ultrapure water for patient washing and drinking, the filter aids in infection control. The filter produces water that is suitable for patient wound cleansing, cleaning of equipment used in medical procedures and washing of surgeon's hands. The filter is not intended to provide water that can be used as a substitute for USP sterile water.

Use Life: The device is intended for long term continuous use. Once it completes its useful life, the filter should be replaced and discarded. Do not attempt to sterilize or reuse it.

Contraindications

Chemical: The HydraGuard 10" UltraFilter - Flush retains biological contaminants. To obtain chemically pure water it is necessary to use the filter in conjunction with other devices such as DI beds or RO systems.

Warnings & Precautions

Pressure & Temperature: The HydraGuard 10" UltraFilter - Flush is intended for a maximum incoming water pressure of 60 psi (4 bar) and a maximum incoming temperature of 27°C (80°F).

Cyclic Use: The HydraGuard 10" UltraFilter - Flush is designed to achieve a maximum of 6,000 on/off cycles.

Replacement: The filter should be replaced when the flow rate begins to noticeably decrease. It is recommended to establish a maintenance schedule of replacing the filter at least every 12 months dependent on water quality.

Water Monitoring: After installation of the HydraGuard 10" UltraFilter - Flush, periodic monitoring of the water is recommended. Water quality is dictated by the intended use and should be established and monitored by the facilities engineer. Nephros is available to assist with establishing guidelines and acceptance criteria as needed.

Filter Installation & Removal

New Install: If this is the first time any reusable cartridge type filter is being installed in a location (i.e. there are no cartridge housings in place), please refer to the second page of these instructions for installation guidance before proceeding with the instructions below

Note: Prior to handling a new filter, wash hands and wear disposable gloves.

- Turn off the water source upstream of the filter and vent any excess pressure from the housing via its bleed valve or flush port valve.
- Remove both the housing bowl/cover and the old filter.
- Open a new filter blister pack and aseptically remove the filter.
- Insert one end of the filter into the head of the housing cap. It may be necessary to use a twisting motion to ensure that the filter is firmly in place and the O-rings seat properly. Re-attach the housing bowl/cover, to the housing cap.
- Open the flush port valve and the upstream water source to prime the new filter.

- Close the flush port valve after 20-30 seconds, and continue to prime the filter for 5 minutes to purge it of trapped air (if the housing has a bleed valve, open it at the same time to assist purging).
- Close the outlet test valve (and bleed valves if present) and verify there are no leaks.

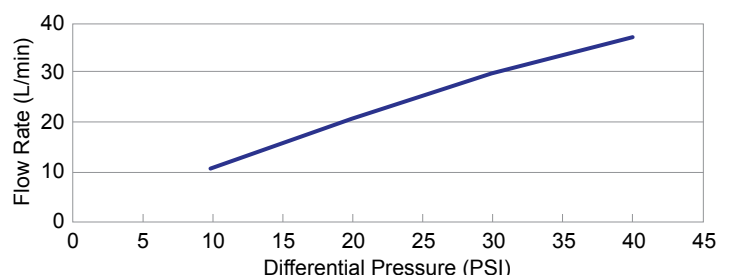
Operation

After a new HydraGuard 10" UltraFilter - Flush is installed, water should be run through the filter for approximately 5 minutes to purge it of trapped air and any manufacturing particulates. The pressure drop across the HydraGuard 10" UltraFilter - Flush generally reduces the flow rate by about 10-20% of the rate without a filter. The HydraGuard 10" UltraFilter - Flush is designed with a flush capability for periodic filter flushing. The filter should operate for up to 12 months of normal use with minimal degradation in flow (dependent on water quality and flush frequency). If the flow rate degrades significantly, the filter should be replaced.

Integrity Testing

- The filter integrity can be verified with a pressure holding test after the filter has been properly primed and there are no connection leaks.
- Turn off the water source and open the inlet test valve to bleed off any residual pressure.
- Connect an air source (compressed air or air pump) to the inlet test port as shown in Housing and Filter Installation Example. Note that a pressure gauge must be installed to monitor the inlet filter pressure to carry out this test.
- Open both test valves, and pressurize the filter inlet; ensure the outlet test port is venting. Raise the air pressure to 15 psi at the filter inlet and allow water to exit from the outlet test port. Do not exceed 30 psi to prevent damage to the filter membrane.
- When water stops coming out from the outlet test port close the outlet test valve and check for external leaks (via pressure gauge).
- Open the outlet test valve and re-pressurize as necessary to reach 15 psi at the filter inlet.
- With the outlet test valve open, close the inlet test valve and allow the pressure to stabilize for 5 to 10 seconds.
- Monitor the pressure gauge and determine the pressure drop for a period of 1 minute.
- If the pressure drops by more than 1 psi over a minute, check for leaks and repeat the test to confirm. If the filter fails, it must be replaced.
- Close the outlet test valve and remove air source. Open water source valve and re-prime filter to return to operation.

Clean Water Flow Rate

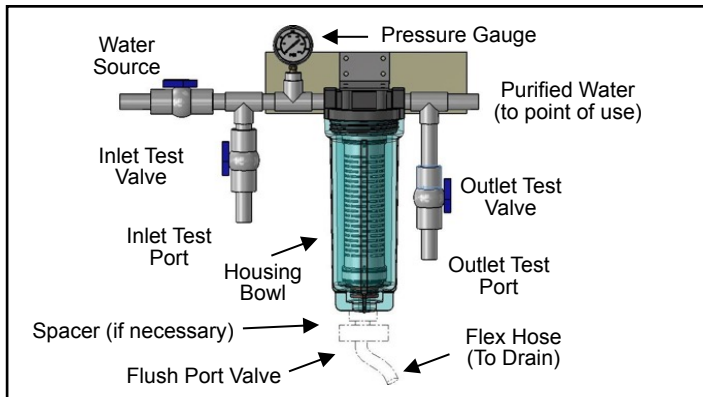


HydraGuard 10" UltraFilter – Flush (continued)

Specifications

Max Inlet Pressure	60 psi (4 bar)
Max Inlet Temperature	27°C (80°F)
Max # On/Off Cycles	6,000
Filter Membrane⁽¹⁾	Medisulfone®
Material	Polysulfone
MW cut-off	15 kDa
Bacterial Retention	> 10 ¹¹ (B. diminuta)
Virus Retention	> 10 ⁸ (PhiX-174)
Endotoxin Retention	> 10 ⁶ EU/ml
Expected Life⁽²⁾	Up to 12 months

Housing and Filter Installation Diagram



Housing Installation

If no cartridge filter housing is currently installed, the initial installation of the HydraGuard-F 10" UltraFilter requires tapping into an existing section of the distribution line between the water source and the equipment and plumbing a siphon resistant drain line, which includes a flush valve, between the flush port of the filter housing and an existing drain. This can be accomplished with a back-flow prevention device (eg. check valve) or maintaining a suitable air gap between the outlet of this line and drain.

It is recommended to incorporate a segment of flexible hose downstream of the flush valve to enable easy removal of the housing bowl for replacing the filter cartridge. Contact Nephros for additional support with housings and install components. A typical installation of a HydraGuard-F 10" UltraFilter with cartridge housing is shown in the Housing and Filter Installation Diagram.

Note: HydraGuard 10" UltraFilter - Flush is only to be installed in reusable flushable cartridge filter housing that are rated to at least 100 psi working pressure and comply with NSF/ANSI Standard 42/61 for material (or made from pure polypropylene with no fillers, colorants, plasticizers or lubricants) and accept 10" 222 O-ring head cartridge filters.

Note: Ensure that the top cap of the housing is oriented such that the inlet flow is delivered to the center (ring section) of the cap and the outlet flow comes from the bowl space as some commercial housings may have reversed inlet/outlet labeling on housing cap). A spacer may be required for longer housings to properly seat the O-rings (contact Nephros for acceptable spacers).

(1) Medisulfone® is a registered trademark of Medica S.p.A.

(2) Expected life based on daily flush frequency (dependent on water quality).

Housing & Plumbing Disinfection














In cases where a HydraGuard 10" UltraFilter - Flush housing is being installed for the first time or the filter is being replaced, it is recommended to disinfect the cartridge housing and downstream plumbing (faucet, equipment, etc.). This applies whether it is a new housing recently installed or an existing housing that may have contained another cartridge type filter.

Note: Disinfection should be performed with a diluted 1:100 bleach/ water solution. Use personal protective equipment (gloves, lab coat, glasses, etc.) when handling the disinfectant, filter and housing to decrease any chances of contaminating the water system.

Note: Prior to handling a new filter, wash hands and wear disposable gloves.

- Turn off water source upstream of the housing and vent any excess pressure from the housing via its bleed valve (if present) or outlet test valve.
- Remove the housing bowl & used filter cartridge and empty water.
- Aseptically remove a new filter from its packaging and install the O- ring end into the top cap of the filter housing.
- Ensure that the flush port valve is closed.
- Fill the housing bowl with 0.5 Liters of a fresh bleach solution prepared as a 1:100 dilution of standard bleach (8.25%) per the manufacturer's instructions.
- Carefully re-assemble the housing bowl containing the bleach solution to the top cap and tighten. Be careful to avoid spillage of the bleach solution.
- Open the upstream water source.
- Slowly open the downstream valve on the equipment or faucet to purge air out of the housing and until disinfectant is observed to be flowing through the system using a chlorine test trip. Close the downstream valve.
- Slowly open the outlet test port valve and confirm the presence of bleach with a chlorine test strip. Close the outlet test valve.
- Allow the disinfectant to dwell for a minimum of 10 minutes, but no more than 30 minutes. Any longer could damage internal components of the equipment or faucet.
- Open the downstream valve and allow water to flush the disinfectant out of the filter housing and the downstream plumbing. To effectively rinse bleach from the filter housing, the flow rate should be at least 10 L/min (2.6 GPM) for 5 minutes.
- Open the flush port valve for approximately 30 seconds to flush disinfectant from the flush port.
- Open the outlet test valve for approximately 30 seconds to flush disinfectant from the outlet test port.
- Test the downstream water to ensure low residual disinfectant levels relative to the inlet water chlorine levels. **If residual level is too high, repeat rinsing steps above until acceptable results are obtained.**

Note: To determine that the chlorine residuals have been effectively removed from the rinse water, Nephros recommends using Serim® Guardian Residual Chlorine Test Strips, 5100A. Follow all instructions from the manufacturer to obtain proper results.

Symbol	Symbol Title	Standard Reference	Standard Title	Explanatory Text
	Manufacturer	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the medical device manufacturer
		ISO 7000	Graphical symbols for use on equipment	
	Use by Date	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the date after which the medical device is not to be used.
		ISO 7000	Graphical symbols for use on equipment	
	Batch Code	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the manufacturer's batch code so that the batch or lot can be identified.
		ISO 7000	Graphical symbols for use on equipment	
	Part Number	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the manufacturer's part number, so that the medical device can be identified.
	Sterilization by Ethylene Oxide	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that has been sterilized using Ethylene Oxide.
		ISO 7000	Graphical symbols for use on equipment	
	DO NOT Resterilize	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that is not to be resterilized.
		ISO 7000	Graphical symbols for use on equipment	
	DO NOT Use if Package Is Damaged and Consult Instructions for Use	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that should not be used if the package has been damaged or open.
		ISO 7000	Graphical symbols for use on equipment	
	Consult Instructions for Use	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the need for the user to consult the instructions for use.
		ISO 7000	Graphical symbols for use on equipment	
	Medical Device	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the item is a medical device.
	Unique Device Identifier	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the medical device contains a Unique Device Identifier.
	Fragile, Handle with Care	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the device shall be handled with care.
		ISO 7000	Graphical symbols for use on equipment	
		ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	Rain	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the device shall be kept away from rain and be kept in dry conditions.
		ISO 7000	Graphical symbols for use on equipment	
		ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	Keep Away from Sunlight	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the device shall not be exposed to sunlight.
		ISO 7000	Graphical symbols for use on equipment	
		ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	Temperature	ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the temperature limits in which the medical device can be safely exposed.
		ISO 7000	Graphical symbols for use on equipment	
		ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	This Way Up	ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Indicates the correct upright position of the distribution packages for transport and/or storage.
		ISO 7000	Graphical symbols for use on equipment	
	Stacking Load	ISO 780	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Indicates the maximum stacking load which may be stacked on the distribution packages.
		ISO 7000	Graphical symbols for use on equipment	

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